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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-20-1186]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Information Collection for Tuberculosis Data from Referring Entities to CureTB to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on December 23, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW,

Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Information Collection for Tuberculosis Data from Referring Entities to CureTB (OMB Control No. 0920-1186, Exp. 06/30/2020)

- Revision - National Center for Emerging Zoonotic and Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CureTB at the Centers for Disease Control and Prevention (CDC) works with domestic and international programs to protect the U.S. public by preventing tuberculosis (TB) disease transmission domestically and internationally, as well as preventing the development of drug resistant TB. These goals are accomplished through CureTB referral and continuity of care services for mobile TB patients.

Lack of treatment adherence and inappropriate selection of medications are prime reasons for the continued emergence and spread of resistant strains of tuberculosis. To combat this, CureTB ensures that patients understand how to remain adherent to treatment regimens, despite moving between nations. CureTB also provides information to the health care team that will be continuing care about each patient's TB strain and tailored medication regimen. CureTB gathers demographic and clinical

information for each patient and connects that individual to appropriate clinical care. This information is also provided on a real-time basis to medical providers and public health authorities in receiving nations so that follow-up with the patient can be expedited.

The respondents are local health departments (LHD) or Immigration and Customs Enforcement (ICE) detention centers within the United States and foreign national TB programs or healthcare facilities in other countries that provide diagnostic and treatment services to individuals affected by TB.

Individual TB patients may also be respondents if critical clinical or contact information is missing from their referral and CureTB follows-up with them to fill-in gaps to complete the referral service. All 50 US states and territories may refer TB patients to the CureTB program. To date, CureTB has also received referrals from Mexico and Guatemala. Local health departments or ICE detention facilities will submit CureTB referral forms as they request referral services. The number of referrals varies widely between respondents.

To ensure adequate referral to treatment occurs, CDC CureTB may need to follow-up with an individual to complete missing data fields concerning clinical or contact information. This is done to ensure continuity of care. Therefore, individuals with TB are also respondents in this information collection. CDC's

CureTB program will also continue working with our public health partners in notifications and referrals for contacts of TB cases. This is a lesser used function of CureTB, but burden is included below. These respondents are health departments.

Finally, CDC staff in the CureTB program also contact the new treating physicians to determine patient outcomes using CureTB Clinician Public Health Department Follow-up Script. The physicians are generally contacted every two months over the course of standard six month TB treatment, for a total of three follow-up contacts per patient.

The revision for this information collection includes a small number of changes to the CureTB Transnational Notification information collection tool for ease of use by the respondents, and adding two pieces of additional data important for clinical decision making and patient contact. Additionally, CDC is clarifying the specific burden attributable to individuals within ICE detention centers by noting this in the Estimated Annualized Burden Hours table. Finally, CDC is updating the number of respondents and associated burden based on program operations over the last 12 months. No other changes are proposed.

OMB approval is requested for three years. Participation in this data collection is voluntary. There are no costs to respondents other than the time required to complete the

referral documents and respond to CDC requests for TB patient outcomes. The total estimated annualized burden is 1,081 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Local Health Departments (LHD) in the United States	CureTB Transnational Notification	70	4	30/60
TB patients referred by LHD	CureTB Transnational Notification	187	1	5/60
TB patients referred by ICE	CureTB Transnational Notification	587	1	45/60
TB treating physicians in new country	Clinician Public Health Department Follow-up Script	870	3	10/60
LHD in the United States	CureTB Contact/Source Investigation (CI/SI) Notification	20	5	30/60

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

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